

The product formulation is:

Part I (M1)	
2-Hexyl Cyanoacrylate	999,550 ppm
Hydroquinone	100 ppm
p-Methoxyphenol	100 ppm
Pure Phosphoric Acid	250 ppm
Part II (M2)	
Pure Gold	1.0000 g
Pure Ethyl Myristate	0.5000 g
FMS*	0.0200 g

*FMS is a specially prepared polymer of 2-hexyl cyanoacrylate and must be used within 24 hours of preparation or will change and be unusable. Further, it must be sterilized within 72 hours.

Each item of this formulation is critical to the proper performance of the product.

2-Hexyl Cyanoacrylate

This cyanoacrylate homolog was chosen because it biodegrades very slowly in blood or any living tissue. The secondary alcohol will biodegrade several thousand times slower than its primary derivative. This very slow degradation rate also lowers greatly the histotoxicity.

Hydroquinone

When the amount of hydroquinone is reduced by half (50 ppm) the product shows low shelf life stability. Large amounts over 100 ppm do not seem to effect the product stability. This inhibitor lowers the effect of the high energy free radicals that may appear in the cyanoacrylate.

p-Methoxyphenol

The slow polymerization of cyanoacrylates even under refrigeration is caused by low energy free radicals. When 100 ppm of p-methoxyphenol is present this slow polymerization is prevented and long term stability is achieved. Less p-methoxyphenol (50 ppm) will not protect the product.

Sulfur Dioxide

The faintest trace of sulfur dioxide is present in the product. One part per million can be seen and less is present. However, this very faint trace adds to the stability of Neuracryl* ml in the ampule.

Gold

Tantalum, platinum and gold are all radiopaque. Gold was best for us because it could be suspended colloiddally in the mixture. One gram of gold is used per device.

Ethyl Myristate

Subbicates, fatty acid esters and other plasticizers, are useful for fastening the polymers of the cyanoacrylates. they also will stabilize the pre-formed polymers of the cyanoacrylates so that they may be used as thickeners. We have chosen ethyl myristate, an esterified, biocompatible fatty acid because of the convenience of purification and

analysis and because it works well to give the formulation the desirable properties.

FMS

FMS is the polymer of 2-hexyl cyanoacrylate formed in a weak, aqueous sodium bicarbonate solutions. The polymer differs in structure and size depending on how it is formed. This polymer will remain stable until M2 can be formulated. The polymer must be formed and dried completely before use. The final formulation of M2 must occur within 24 hours because the ethyl myristate stabilized FMS until sterilization can be performed. After sterilization the product is stable for several years.

Neuracryl M

M1 and M2 are mixed immediately before use. The mixture should be used within 4 hours after mixing. If there is a delay, the syringe should be turned over several times a minute to resuspend the gold which will be settled.

What is claimed is:

1. A composition for creating therapeutic vascular occlusions in an animal comprising a mixture of:

(a) Part 1 comprised of 2-hexyl cyanoacrylate, hydroquinone, p-methoxyphenol and phosphoric acid; and

(b) Part 2 comprising gold metal powder, [ethyl myristate] a fatty acid ester and a [sterilized] polymer of 2-hexylcyanoacrylate [in weak aqueous bicarbonate solution]

2. The composition of claim 1 wherein Part 1 comprises about 100 PPM hydroquinone, 100 PPM p-methoxyphenol, 250 PPM phosphoric acid and the remainder 2-hexyl cyanoacrylate.

3. The composition of claim 2 wherein Part 2 comprises about 65 percent by weight gold, about 30 percent by weight ethyl myristate and the remainder said sterilized polymer of 2-hexylcyanoacrylate [in weak aqueous bicarbonate solution]

4. The composition of claim 1 wherein Part 2 includes sulfur dioxide as a stabilizer.

5. A method for creating therapeutic vascular occlusions in an animal needing therapeutic vascular occlusion comprising the steps of:

(a) Mixing together Part 1 comprised of 2-hexyl cyanoacrylate, hydroquinone, p-methoxyphenol and phosphoric acid with Part 2 comprising gold metal powder, [ethyl myristate] and a [sterilized] polymer of 2-hexylcyanoacrylate [in weak aqueous bicarbonate solution] and administering

(b) [injecting] the mixture into a vascular site needing occlusion with the gold metal powder suspended in the mixture.

* * * * *